New Claims

Amendments to the Claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

Claim Listing

1. (Currently amended) A method for enhancing the effect of a vaccine, the method comprising administering to a patient in need thereof, a vaccine ~~pharmaceutical~~ composition comprising pharmaceutically acceptable particles, the particles comprising

~~(i)~~ a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with

~~(ii)~~ ~~a~~ an ~~first~~ adjuvant chemical which increases the effect of the biologically active agent, said adjuvant chemical ~~selected from one or more~~ being selected from the group consisting of:

A) polyornithine,

B) a water soluble vitamin or water soluble vitamin derivative,

C) a positively charged cationic block copolymer or a positively charged cationic surfactant,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine; ~~and~~

~~(iii) a pharmaceutically acceptable carrier or diluent;~~ subject to the following provisos

a) ~~when the chemical (ii) above is selected from D) or E), the biologically active agent is an agent that generates a protective immune response in an animal to which it is administered;~~

~~b)~~ when the adjuvant chemical ~~(ii)~~ ~~above~~ is selected from A) ~~and the biologically active agent is an agent that generates a protective immune~~

~~response in an animal to which it is administered~~, the composition is for administration to a mucosal surface,

~~c)~~ b) when the adjuvant chemical ~~(ii) above~~ is selected from C) ~~and the biologically active agent is an agent that generates a protective immune response in an animal to which it is administered~~, the composition does not contain a polyacrylic acid, and

~~d)~~ c) when the adjuvant chemical ~~(ii) above~~ is selected from G) ~~and the biologically active agent is an agent that generates a protective immune response in an animal to which it is administered~~, the ~~carrier or diluent of (iii)~~ particle is a microsphere or liposome.

Claim 2 (Cancelled)

3. (Currently amended) The ~~composition~~ method of claim 1 wherein the adjuvant chemical acts as an immunostimulant.

4. (Currently amended) The ~~composition~~ method of claim 1 wherein the ~~said~~ adjuvant chemical is selected from one or more of;

A) ~~the poly ornithine~~ polyornithine ~~has~~ having a molecular weight from 5 to 150kDa;

B) ~~the water soluble vitamin or water soluble vitamin derivative is~~ vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),

C) ~~the~~ a cationic block copolymer or ~~the~~ a cationic surfactant, ~~is~~ positively charged by means of NH_2^+ groups

D) ~~the~~ a complexing agent that forms complexes with fatty acids, or

E) ~~the clathrate is a~~ cyclodextrin or a derivative thereof.

5. (Cancelled)

6. (Currently amended) The ~~composition~~ method of claim ~~5~~ 1 wherein the ~~particle is a microsphere or liposome~~ particles are microspheres or liposomes.

7. (Currently amended) The ~~composition~~ method of claim 6 ~~which comprises a microsphere~~ wherein the particles are microspheres.

8. (Currently amended) The ~~composition~~ method of claim 7 wherein the ~~microsphere is~~ microspheres are prepared using a high molecular weight polymer.

9. (Currently amended) The ~~composition~~ method of claim 8 wherein the polymer has a molecular weight of 100kDa or more.

10. (Currently amended) The ~~composition~~ method of claim 7 wherein the microsphere comprises poly-(L-lactide).

Claim 11 (Cancelled)

12. (Currently amended) The ~~composition~~ method of claim 1 ~~which~~ wherein the vaccine composition is administered to a mucosal surface of the animal or administered parenterally to the animal.

13. (Currently amended) The ~~composition~~ method of claim 1 ~~2~~ ~~which~~ wherein the vaccine composition further comprises a second adjuvant.

Claims 14-25 (Withdrawn)

26. (Currently amended) The ~~composition~~ method of claim ~~4~~ 30 wherein

~~A)~~ the complexing agent forms complexes with deoxycholic acid~~; or~~

~~B) the clathrate is dimethyl-β-cyclodextrin~~ .

27. (New) The method of claim 1 wherein the adjuvant chemical is A) polyornithine having a molecular weight from 5 to 150 kDa.

28 (New) The method of claim 1 wherein the adjuvant chemical is B) a water soluble vitamin or water soluble vitamin derivative comprising vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate).

29. (New) The method of claim 1 wherein the adjuvant chemical is C) a cationic block copolymer or a cationic surfactant, positively charged by means of NH_2^+ groups.

30. (New) The method of claim 1 wherein the adjuvant chemical is E) a complexing agent that forms complexes with fatty acids.

Old Claims

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of the claims in the application.

Listing of Claims

1. (Currently amended) A pharmaceutical composition comprising

(i) a biologically active agent;

(ii) ~~an~~ a first adjuvant chemical which increases the effect of the biologically active agent, said chemical selected from one or more of:

A) ~~a polyamino acid~~ polyornithine,

B) a water soluble vitamin or water soluble vitamin derivative,

C) a positively charged cationic ~~pluronics~~ block copolymer or a positively charged cationic surfactant,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine; and

(iii) a pharmaceutically acceptable carrier or diluent; subject to the following provisos

a) when the chemical (ii) above is selected from D) or E), the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered;

b) when the chemical (ii) above is selected from A) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the composition is for administration to a mucosal surface,

c) when the chemical (ii) above is selected from C) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the composition does not contain a polyacrylic acid, and

d) when the chemical (ii) above is selected from G) and the biologically active agent is an agent ~~which is capable of generating~~ that generates a protective immune response in an animal to which it is administered, the carrier or diluent of (iii) is a microsphere or liposome.

2. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the biologically active agent is an agent that ~~is capable of generating~~ generates a protective immune response in an animal to which it is administered.

3. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the ~~said~~ adjuvant chemical ~~can act~~ acts as an immunostimulant.

4. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the said adjuvant chemical is selected from one or more of;

A) the poly-ornithine has a~~, for example of~~ molecular weight from 5 to 150kDa;

B) the water soluble vitamin ~~vitamins~~ or water soluble vitamin derivative ~~derivatives~~ is ~~such as~~ vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),

C) the cationic ~~pluronics which are~~ block copolymer ~~copolymers~~ or the cationic surfactant is ~~surfactants which are~~ positively charged by means of~~, in particular with~~ NH_2^+ groups

D) the complexing agent forms ~~agents which form~~ complexes with fatty acids ~~such as deoxycholic acid~~, or

E) the clathrate is a cyclodextrin or a derivative thereof ~~cyclodextrins and their derivatives such as dimethyl β cyclodextrin~~.

5. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the carrier comprises a particle.

6. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 5 wherein the particle is a microsphere or liposome.

7. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 6 which comprises a microsphere.

8. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 7 wherein the microsphere is prepared using a high molecular weight polymer.

9. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 8 wherein the polymer has a molecular weight of 100kDa or more.

10. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 7 wherein the microsphere comprises poly-(L-lactide).

11. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 wherein the ratio of the chemical (ii) to the carrier (iii) is from 99:1 to 9:1 w/w.

12. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 1 which is ~~adapted for administration to a mucosal surface or is suitable for parenteral administration~~ administered to a mucosal surface of the animal or administered parenterally to the animal.

13. (Currently amended) ~~A~~ The composition ~~according to~~ of claim 2 which further comprises a ~~further~~ second adjuvant.

14. (Withdrawn) A method of producing a prophylactic or therapeutic vaccine, which method comprises encapsulating a polypeptide which is capable of producing a protective immune response in a first polymeric material which has a high molecular weight, in the presence of a second polymeric material which increases the biological effect of the composition.

15. (Withdrawn) A method of protecting a mammal against infection, which method comprises administration of a composition according to claim 1 to a mammal.

16. (Withdrawn) A method according to claim 15 wherein the composition is applied to a mucosal surface.

17. (Withdrawn) A method according to claim 16 wherein the mucosal surface comprises an intranasal surface.

18. (Withdrawn) A microsphere comprising a polymeric carrier and an S-layer protein.

19. (Withdrawn) A microsphere according to claim 18 wherein said S-layer protein is coated on the surface of the microsphere.

20. (Withdrawn) A microsphere according to claim 18 which further comprises an agent that is capable of generating a protective immune response in an animal to which it is administered.

21. (Withdrawn) A microsphere according to claim 20 wherein one or more of said agents are linked to the S-layer protein.

22. (Withdrawn) A pharmaceutical composition comprising a microsphere according to claim 19.

23. (Withdrawn) A pharmaceutical composition according to claim 22 wherein said composition is a vaccine, intended to produce a protective immune response against a bacterium, and said S-layer protein is derived from said bacterium.

24. (Withdrawn) The use of a chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant, provided that in the case of A), the immunostimulant is applied to a mucosal surface, in the case of C, the compound is used in the absence of a polyacrylic acid.

25. (Withdrawn) The use of an adjuvant chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant in the production of a vaccine for use in prophylactic or therapeutic treatment, provided that in the case of A), the immunostimulant is used in a vaccine which is

applied to a mucosal surface, in the case of C), the compound is used in the absence of a polyacrylic acid.

26. (New) The composition of claim 4 wherein

A) the complexing agent forms complexes with deoxycholic acid; or

B) the clathrate is dimethyl-β-cyclodextrin.